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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,859	06/25/2003	Douglas Casterlin	3081	2105

7590 06/13/2006  
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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/602,859	Applicant(s) CASTERLIN ET AL.	
	Examiner Jacob Cheu	Art Unit 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. <u>6/5/2006</u> .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____.  | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-11, drawn to a diagnostic test device, classified in class 422, subclass 119.
  - II. Claims 12-15, drawn to a process of making a diagnostic test device, classified in class 436, subclass 164.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product made and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of group I, can be made by another and materially different process, such as spin coating technology.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the search required for one group is not required for the other, and the search required for one group is not required for the other, therefore , therefore restriction for examination purposes as indicated is proper.
4. A telephone call was made to Mr. Jaskiewicz on 6/5/2006 to request an oral election to the above restriction requirement, and applicant elects group I, claims 1-11, with traverse.
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 3, 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 3, line 3, it is not clear what applicant means “be inserted there-between”. Applicant needs to clarify.

With respect to claim 8, line 3, it is not clear what applicant means “side-by-side relationship”.

With respect to claim 9, line 2, it is not clear what applicant means “plurality of test strips are attached together.” Does applicant means physically these test strips are attached together ? If so, applicant needs to point the support from specification to the examiner.

Similarly, claim 10 also suffers the same problem as indicated in claim 9.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 3, 6, 8-9, are rejected under 35 U.S.C. 102(b) as being anticipated by Willis et al. (EP 0837320).

Willis et al. teach an assay device for detection of analytes in a sample. The device taught by Willis comprises a thing flat core member having grooves indented into a face thereof (See Figure 2 component 26 is groove), an immunoassay test strip (component 12 in Figure 3-4), and means on the edges of the grooves (bottom portion of groove 26 in Figure 2) for retaining the test strip in respective groove.

With respect to claim 3 and 8, each groove of the device taught by Willis et al. is spaced apart, and each groove can be inserted of one test strip. Surpa.

With respect to claim 6, the device of the grooves are positioned in parallel (See Figure 3-4).

9. Claims 1, 3-4, 6, 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Tydings et al. (US 6805838).

Tydings et al. teach an assay device for detection of analytes in a sample. The device taught by Tydings comprises a thing flat core member having grooves indented into a face thereof (See Figure 3-4; component 14 is groove), an immunoassay test strip (component 12 in Figure 3-4), and means on the edges of the grooves (bottom portion of groove 14 in Figure 3) for retaining the test strip in respective groove.

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With respect to claim 3 and 8, each groove of the device taught by Tydings et al. is spaced apart, and each groove can be inserted of one test strip. Surpa.

With respect to claim 4, the material of the core can be of plastic (Col. 2, line 38-45).

With respect to claim 6, the grooves are positioned in parallel. Supra.

With respect to claim 10, Tydings et al. teach using backing sheet for the device and the test strips also attached to the backing sheet (See Figure 2 and Figure 4).

With respect to claim 11, the device also comprises a front panel to enclose the test strip and having openings to provide access to the test strip (See Figure 1 and 3).

10. Claims 1-6, 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al. (US 6818452).

Wong et al. teach a device for analyzing target molecule in a sample. The device comprises a thin flat core member having at least one groove indented into a face thereof, where an immunoassay test strip is placed in said groove (see component 441 as test strip and component 418 as groove for placing said test strip in Figure 8) and means on the edges of grooves for retaining test strips in respective groove (See Figure 8, the bottom of the groove 418 can be means for retaining test strips).

With respect to claims 2-3, the projections on the opposed longitudinal edges of grooves (component 414) can be used to retaining test strips (See Figure 8).

With respect to claim 4, Wong et al. also teach the material for the device can be of plastics (Col. 4, line 30-45).

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With respect to claim 5, Wong et al. teach a pluralities of nibs (component 414) projections on the grooves as means for retaining test strips in the device (Figure 8).

With respect to claim 6, 8, Wong et al. disclose that the grooves are positioned in parallel (See Figure 8-9).

With respect to claim 10, Wong et al. disclose that the test strips are attached to the backing absorbent (Col. 2, line 60 to Col. 3, line 10).

With respect to claim 11, Wong et al. teach that the device comprises a front panel for access of test strip and allow for reviewing test results (See Figure 8-9).

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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13. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tydings et al. in view of Casterlin et al. (US 6403383).

Tydings et al. reference has been discussed but does not explicitly teach using a test strip having two-sided grooves for placing test strips for analysis of analytes.

Casterlin et al. teach using two-sided grooves having test strips for immunoassay analysis. The device provides advantages of time and cost saving (Col. 1, line 40 to Col. 5; Col. 2, line 55-65).

Therefore, It would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Tydings et al. with the two-sided grooves as taught by Casterlin et al. for placing test strips in order to save time and cost for a mass screening purpose.

### ***Conclusion***

14. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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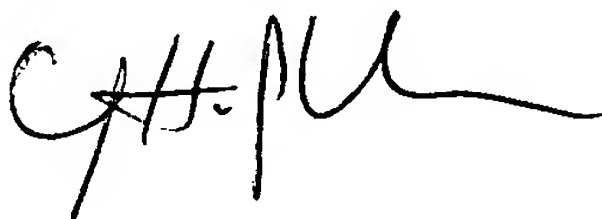
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Jacob Cheu

Examiner

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June 8, 2006



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06/09/06